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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,590	07/29/2003	Peter S. Lu	34170-701.501	4993

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EXAMINER

LUCAS, ZACHARIAH

ART UNIT	PAPER NUMBER
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1648

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/06/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/630,590	LU ET AL.	
	Examiner	Art Unit	
	Zachariah Lucas	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3-8, 10-22 and 24-28 is/are pending in the application.
- 4a) Of the above claim(s) 6-8, 27 and 28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-5, 10-15, 21, 22, and 24-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3-8-07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Currently, claims 1, 3-8, and 10-22, and 24-28 are pending.
2. In the prior action, the Final action mailed on October 31, 2006, claims 1, 3-8, and 10-15, and 24-26 were pending and rejected.
3. In the Response of January 31, 2007, the Applicant amended claims 6, 21, 22, and 24; and added claims 27 and 28.
4. Claims 6-8 have been amended to read on a composition. As such, the claims no longer read on elected subject matter, and are therefore withdrawn from examination. Since new claims 27 and 28 are also drawn to this composition, these claims are also withdrawn from examination.
5. Claims 1, 3-5, 10-15, 21, 22, and 24-26 are under consideration.

Claim Objections

6. **(Prior Objection- Withdrawn)** Claims 21 and 22 were objected to because of the following informalities: these claim further describe the “method of claim 1, 6, 10.” In view of the amendments to the claims, the objection is withdrawn.

7. **(New Objection)** Claim 24 is objected to because of the following informalities: it appears that the phrase “with heterologous domain” in line 6 of the claim should read - - with a heterologous domain- -. Appropriate correction is required.

Claim Rejections - 35 USC § 112

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8. **(Prior Rejection- Withdrawn)** Claims 6-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite because it was unclear if the claims were drawn to a method or to a composition. In view of the amendments of the claims, the rejection is withdrawn.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. **(Prior Rejection- Maintained)** Claims 1, 3-8, 10-13, 15, 21, 22, and 24-26 were rejected under 35 U.S.C. 103(a) as being unpatentable over the teachings of Davis (U.S. 5,610,077) in view of Thomas et al. (Oncogene 20: 5431-39) and Bleul (U.S. 5,753,233). The rejection is withdrawn from claims 6-8, which no longer read on the elected invention.

The Declaration filed on January 31, 2007 under 37 CFR 1.131 has been considered but is ineffective to overcome the Thomas reference. A Declaration under 37 CFR 1.131 must be signed by one of the parties identified in MPEP 715.04, which generally means by all of the named inventors or (in relevant part) by the assignee or other party in interest when it is not possible to produce the affidavit or declaration of the inventor. In the present case, the Declaration was signed by one of the named inventors (Dr. Lu), who is also the CEO and President of the assignee corporation. However, Dr. Lu is not the sole inventor, and is not indicated to be the sole inventor of the claims under rejection; and neither the Declaration nor the

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arguments presented in the Response provide any statement to the effect that it is not possible to get the signatures of each of the named inventors. The Declaration has therefore not been properly executed, and is therefore not found persuasive.

The Applicant additionally traverses the rejection based on the prior disclosure in the parent provisional application 60/309,841. The provisional application teaches that the HPV-66 E6 protein binds to the BAI-I protein (another name for MAGI-I). Page 99 (Table 2, page 11). Thus, the provisional application teaches a species of the presently claimed invention. However, the provisional application does not provide the Applicant with priority over Thomas with respect to the detection of every oncogenic strain of HPV. In particular, while the provisional application indicates that the E6 protein of each of the oncogenic HPV strains 16, 18, and 31 "are PDZ ligands" based on the presence of a PL motif in each of these E6 proteins, it does not teach that each of these E6 proteins is capable of binding specifically to the PDZ domain 2 of MAGI-1. Pages 87-88. I.e., the provisional application identifies these E6 proteins a ligands to PDZ polypeptides in general, but does not conclude or even suggest that they are each a ligand for the MAGI-1 protein, or for PDZ domain 2 of that protein.

In order to predate a reference that teaches a species of a claimed invention, the Applicant is required to show either prior completion of the claimed species or prior completion of a different species coupled with a showing that the claimed species would have been an obvious modification of the species completed by applicant. See e.g., MPEP 715.03. In the present case, the Thomas reference (in combination with the other cited references) renders obvious one species of the claimed invention- the embodiment where the HPV is HPV 18. The parent provisional application of the current application, the '841 application, also only provides

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support for one species of the claimed method, the embodiment wherein the HPV is HPV 66.

There is no showing that this embodiment renders obvious the other species, particularly the species taught by Thomas. Thus, the Applicant's arguments regarding the priority to the '841 application are not found persuasive.

As neither the Declaration nor the additional arguments have been found persuasive, the rejection is maintained for the reasons above, and the reasons of record.

11. **(Prior Rejection- Maintained)** Claim 14 was rejected under 35 U.S.C. 103(a) as being unpatentable over Davis in view of Bleul and Thomas as applied above, and further in view of Kehmeier et al. (Virology 299: 72-87). Claim 14 has been amended in a similar manner to claims 1 3-8, 10-13, and 15 as described above. The Applicant traverses this rejection on the same basis as described above. The rejection is therefore maintained for the reasons indicated above and of record.

12. **(Prior Rejection-Withdrawn)** Claims 24-26 were rejected under 35 U.S.C. 103(a) as being unpatentable over the teachings of Davis (U.S. 5,610,077) in view of Glaunsinger et al. (Oncogene 19: 5270-80) and Bleul (U.S. 5,753,233). In view of the amendment of the claim, the rejection is withdrawn.

Double Patenting

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed.

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Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. **(Prior Rejection- Maintained)** Claims 1, 3-8, 10-15, and 24-26 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, 4, 8, 9, and 10 of copending Application No. 10/847,818 further in view of the teachings of Thomas. The rejection is withdrawn from claims 6-8. The Applicant traverses the rejection on the same basis asserted with respect to the obviousness rejections above. Because the arguments with respect to the Thomas reference were not found persuasive for the reasons indicated above, this rejection is also maintained.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

15. **(Prior Rejection- Withdrawn)** Claims 24-26 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, 4, 8, 9, 10 of copending Application No. 10/847,818 in view of Glaunsinger et al. (*supra*). In view of the amendment of these claims, this rejection is withdrawn.

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16. **(Prior Rejection- Maintained)** Claims 1, 3-8, 10-15, and 24-26 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15 of copending Application No. 11/053076. As no arguments have been presented in traversal of the rejection, the rejection is maintained.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

17. No claims are allowed.

18. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

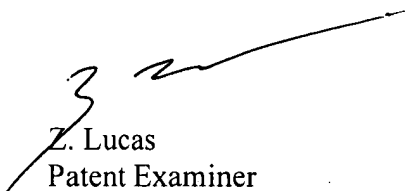
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

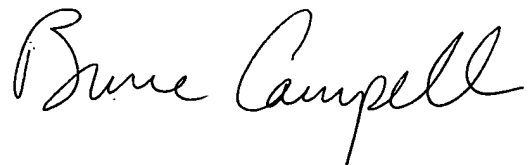
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Z. Lucas
Patent Examiner



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